

Notice of References Cited

Application/Control No.

09/589,589

Applicant(s)/Patent Under
Reexamination
HIGH ET AL.

Examiner

Brian Whiteman

Art Unit

1633

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U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 97/39776 ✓	10-1997	WIPO	Trapnell et al.	-- --
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	✓ Potter et al., Review- The use of immunosuppressive agents to prevent neutralizing antibodies against a transgene product, 1999, ANN. NY ACAD. SCI., Vol. 875, pp. 159-174
	V	✓ Verma et al, Gene therapy-promises, problems and prospects, 1997, NATURE, Vol. 389, pp. 239-242
	W	✓ Anderson, Human gene therapy, 1998, NATURE, Vol. 392, pp. 25-30
	X	✓ Smith et al., Transient immunosuppression permits successful repetitive intravenous administration of an adenovirus vevtor, 1996, GENE THERAPY, Vol. 3, pp. 496-502

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	✓ Kay et al., Evidence for gene transfer and expression of factor IX in haemophilia B patients treated with an AAV vector, 2000, NATURE GENETICS, Vol. 24, pp. 257-261
	V	✓ Jooss et al., Cyclophosphamide diminishes inflammation and prolongs transgene expression following delivery of adenoviral vectors to mouse liver and lung, 1996, HUMAN GENE THERAPY, Vol. 7, pp. 1555-1566
	W	Fang et al., Gene therapy for hemophilia B: Host immunosuppression prolongs the therapeutic effect of adenovirus-mediated factor IX expression, 1995, HUMAN GENE THERAPY, Vol. 6, pp. 1039-1044
	X	Rubanyi, The future of human gene therapy, 20001, MOLECULAR ASPECTS OF MEDICINE, Vol. 22, pp. 113-142

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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 48/00	A1	(11) International Publication Number: WO 97/39776 (43) International Publication Date: 30 October 1997 (30.10.97)
(21) International Application Number: PCT/US97/06199 (22) International Filing Date: 15 April 1997 (15.04.97) (30) Priority Data: 08/634,774 19 April 1996 (19.04.96) US (71) Applicant: GENETIC THERAPY, INC. [US/US]; 938 Clopper Road, Gaithersburg, MD 20878 (US). (72) Inventors: TRAPNELL, Bruce, C.; 4023 Byrd Road, Kensington, MD 20895 (US). YEI, Soonpin; 8672F Via Malloch Drive, La Jolla, CA 92037 (US). McCLELLAND, Alan; 23709 Woodfield Road, Gaithersburg, MD 20882 (US). KALEKO, Michael; 8 Hearthstone Court, Rockville, MD 20854 (US). SMITH, Theodore; 3346 Knolls Parkway, Ijamsville, MD 21754 (US). (74) Agents: LILLIE, Raymond, J. et al.; Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, 6 Becker Farm Road, Roseland, NJ 07068 (US).		(81) Designated States: AU, CA, JP, NZ, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: GENE THERAPY INVOLVING CONCURRENT AND REPEATED ADMINISTRATION OF ADENOVIRUSES AND IMMUNOSUPPRESSIVE AGENTS (57) Abstract <p>A method of effecting a gene therapy treatment in a host which comprises the steps of: (a) administering to a host concurrently (i) an adenoviral vector including at least one DNA sequence encoding a therapeutic agent, (ii) deoxyspergualin, and (iii) cyclophosphamide; (b) discontinuing the administration of said adenoviral vector and said deoxyspergualin, and said cyclophosphamide; and (c) repeating the administration of the adenoviral vector deoxyspergualin, and the cyclophosphamide at least once. The repeated course of treatment of administration of an adenoviral vector, deoxyspergualin, and the cyclophosphamide provides for continued or increased expression of the at least one DNA sequence encoding the therapeutic agent.</p> <p><i>Same species as mammal</i></p> <p><i>1) in conjunction</i></p> <p><i>2) first, concurrently, follow gt</i></p>		